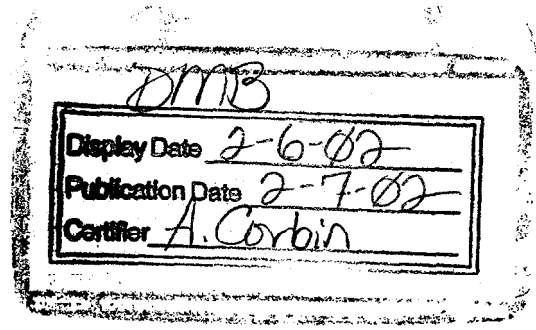
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0785]



Agency Information Collection Activities; Submission for OMB Review; Comment Request; Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the* **Federal Register].**

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

oc01281

N-1

Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics

In **the Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biological Products." In response to comments and on its own initiative, FDA made several revisions to the draft guidance. The agency announced the availability of a revised draft guidance in **the Federal Register** of July 31, 2000 (65 FR 46674).

The draft guidance is intended to assist developers of drug and biological products used for medical imaging in planning and coordinating the clinical investigations of and submitting various types of applications for, such products.

The draft guidance also provides information on how the agency will interpret and apply provisions in the final rule, published in **the Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The final rule describes certain types of indications for which FDA will approve diagnostic radiopharmaceuticals and lists factors that the agency will consider in evaluating the safety and effectiveness of a diagnostic radiopharmaceutical drug or biological product under the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act (the PHS Act), respectively.

The draft guidance applies to medical imaging agents that are used for diagnosis and monitoring and that are administered in vivo. Such agents include contrast agents used with medical imaging techniques such as radiography, computed tomography, ultrasonography, and magnetic resonance imaging, as well as radiopharmaceuticals used with imaging procedures such as single-photon emission computed tomography and positron emission tomography. The draft guidance is not intended to apply to possible therapeutic uses of these agents or to in vitro diagnostic products.

Description: The draft guidance is intended to assist developers of drug and biological products used for medical imaging in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance provides information on how

the agency will interpret and apply provisions of the existing regulations regarding the content and format of an application for approval of a new drug (2 1 CFR 3 14.50) and the content of a biological product application (21 CFR 601.25). The draft guidance also provides information on how the agency will interpret and apply the final rule on the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring (64 FR 26657). The final rule, by adding part 3 15 (21 CFR part 3 15), clarifies requirements for the evaluation and approval of drug and biological radiopharmaceutical$ under the authority of the act and the PHS Act.

Existing regulations, which appear primarily in parts 314 and 601 (21 CFR parts 314 and 601), specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of new drugs and biological products. This information is usually submitted as part of a new drug application (NDA) or a biological license application, or as a supplement to an approved application. Part 3 15 contains regulations that clarify what information is relevant for diagnostic radiopharmaceuticals. This revised draft guidance supplements these regulations. Under part 3 15 and the revised draft guidance, information required under the act and the PHS Act to establish safety and effectiveness would still have to be reported.

Description of Respondents: Developers of medical imaging drugs and biological products, including contrast drug products and diagnostic radiophatmaceuticals.

Burden Estimate: The final rule on in vivo radiopharmaceuticals used for diagnosis and monitoring set forth an estimated annual reporting burden on the industry that would result from that rulemaking (64 FR 26657). OMB has approved this collection of information until July 31, 2002, under OMB control number 0910-0409. This revised draft guidance on the development of medical imaging drugs and biological products is in part intended to explain how FDA will interpret and apply the final rule. Thus, the estimated annual reporting burden of the draft guidance is the same as that of the final rule, with one change. In addition to the diagnostic radiopharmaceuticals that are the subject of the final rule, the revised draft guidance also addresses

the development of contrast drug products, which FDA evaluates and approves under part 314, but which are not affected by the final rule.

Table 1 in this document provides an estimate of the annual reporting burden for contrast drug products. FDA estimates that the potential number of respondents who would submit applications or supplements for contrast drug products would be one. Although FDA did not approve any NDA's for contrast drugs (there are no biological contrast drug products) in fiscal year 1999, for purposes of estimating the annual reporting burden, the agency assumes that it will approve one contrast drug each fiscal year. The annual frequency of responses for contrast drugs is estimated to be one response per application or supplement. The hours per response, which is the estimated number of hours that an applicant would spend preparing the information to be submitted for a contrast drug in accordance with this draft guidance, is estimated to be approximately 2,000 hours.

The revised draft guidance would not impose any additional reporting burden because safety and effectiveness information is already required by existing regulations. In fact, clarification by the guidance of FDA's standards for evaluation of medical imaging drugs and biological products is expected to reduce the overall burden of the information collection. FDA received no comments on the analysis of information collection burdens stated in the notice of availability of the draft guidance published on October 14, **1998.** In the **Federal Register'** of July 3 1, 2000 (65 FR 46674), FDA requested comments on the revised proposed collection of information. The agency received no comments.

TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN'

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Contrast Drugs	1	1	1	2,000	2,000
Total					2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 1-31-02

January 31, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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